

## **REMARKS**

### **I. Rejoinder Of Groups II & III**

The Applicants gratefully acknowledge that the Examiner has rejoined Groups II & III in the present Office Action and confirm that Claims 1-18 and 21 are now pending for examination. Consequently, the Applicants have modified the status identifiers of the affected claims from “Withdrawn” to “Original”. Further, the Applicants have reamended Claims 8, 9 and 13 as dependent from Claim 7 as recited in the original claim set.

### **II. Species Elections**

The Examiner states that the claims now require species elections due to an alleged lack of unity of invention as a consequence of the above rejoinder of Groups II & III. *Office Action pg 2*. These proposed species elections can be summarized as follows:

In Claims 5 & 10, a species election is required as to a portion of SEQ ID NO: 93 from a properly constructed Markush group.

In Claim 8, a species election is required to an encoded protein from a properly constructed Markush group.

In Claim 9, a species election is required to a promoter sequence from a properly constructed Markush group.

In Claim 16, a species election is required to a host cell species from a properly constructed Markush group that also limits Claim 15.

The Examiner is reminded that PTO decisions are reviewed using the standard set forth in the *Administrative Procedure Act*, 5 U.S.C. § 706. *Dickinson v. Zurko*, 527 U.S. 150, 154 (1999). Under that statute, actions are set aside that are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. Moreover, factual findings are set aside that are unsupported by substantial evidence. *In re McDaniel*, 293 F.3d 1379, 1382 (Fed. Cir. 2002).

The Applicants traverse these species elections for the reasons presented below.

**A. Proper Markush Groups Do Not Require Restriction**

The Applicants' Markush groups in Claims 5, 8-10, and 16 comport with the standard MPEP guidelines associated with evaluating a Restriction Requirement:

The members of the Markush group ... ordinarily must belong to a recognized physical or chemical **class** or to an art-recognized **class**.

*MPEP 803.02: Markush Claims* [emphasis added].

**1. Claims 5 & 10 Do Not Require A Species Election**

In Claims 5 & 10 SEQ ID NOS: 91, and 94-144 meet the “physical/chemical/art-recognized class” requirement. Nucleotide sequences are physically and chemically within the same class, and are recognized by those having ordinary skill in the art as belonging to the same class. The Examiner is incorrect when arguing that nucleic acids of different sequences belong to a different physical and/or chemical class.

Further, the Examiner must realize that these nucleic acid portions all contain significant overlapping segments of identical nucleotide sequence. Consequently, the Applicant's Markush group members comport with the standard guidelines for not requiring a Restriction Requirement:

If the members of the Markush group are ... so closely related that a search and examination of the entire claim can be made without serious burden, the examiner **must** examine all the members of the Markush group in the claim on the merits, even though they may be directed to independent and distinct inventions ...

*MPEP 803.02: Markush Claims* [emphasis added]. These Markush elements meet the “closely related” requirement because they are all nucleic acids having sequences of high homology. The Applicants' point to the underscored sentence above to reiterate that it is not relevant if the Examiner continues to believe that independent and distinct inventions are still present, the pending Restriction Requirement is, by law, unreasonable and must be withdrawn.

The Applicants respectfully request that the Examiner reconsider this species election.

**2. Claim 8 Does Not Require A Species Election**

In Claim 8, the encoded proteins listed in the properly constructed Markush group meet the “physical/chemical/art-recognized class” requirement. All proteins are physically and chemically within the same class, and are recognized by those having ordinary skill in the art as belonging to the same class (i.e., for example, amino acid

polymers). The Examiner is incorrect when arguing that difference amino acid sequences necessarily belong to a different physical and/or chemical class.

The Applicants respectfully request that the Examiner reconsider this species election.

**3. Claim 9 Does Not Require A Species Election**

In Claim 8, the encoded proteins listed in the properly constructed Markush group meet the “physical/chemical/art-recognized class” requirement. All recited promoters are physically and chemically within the same class, and are recognized by those having ordinary skill in the art as belonging to the same class (i.e., for example, nucleic acid polymers). The Examiner is incorrect when arguing that different nucleic acid sequences necessarily belong to a different physical and/or chemical class.

The Applicants respectfully request that the Examiner reconsider this species election.

**4. Claim 16 Does Not Require A Species Election**

In Claim 16, the host cells listed in the properly construction Markush group meet the “physical/chemical/art-recognized class” requirement. All recited host cells are within the same art-recognized class (i.e., for example, living biological cells having the capability of being transfected and subsequently grown in culture). The Examiner is incorrect when arguing that host cells from different species necessarily belong to a different physical and/or chemical class.

The Applicants respectfully request that the Examiner reconsider this species election.

**II. Default Election**

The Applicants provide an election of the Examiners' offered species elections only because required to do so under 35 U.S.C. § 121. If the Examiner decides not to reconsider the species elections, the Applicants choose:

SEQ ID NO: 144 from Claims 5 & 10;

Factor IX from Claim 8;

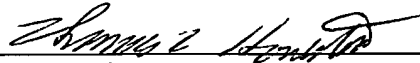
Human Factor IX promoter from Claim 9; and

Mammalian host cell from Claim 16 (and therefore, Claim 15).

**CONCLUSION**

The Applicants believe that the arguments and claim amendments set forth above traverse the Examiner's rejections and, therefore, request that all grounds for rejection be withdrawn for the reasons set above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicants encourage the Examiner to call the undersigned collect at 617.984.0616.

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